

Serial No. 10/007,158
A0000483-01

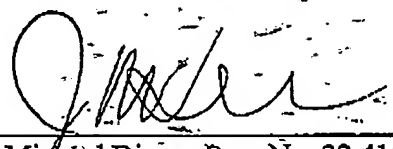
treatment with the dosage regimen of claim 9. The subjects in Applicants study had more severe acne than those evaluated by Redmond. Group 1 had a mean lesion count of 77. Group 2 had mean lesion counts of 70. The lower dosage of estrogen still produced a 40 to 50% reduction in lesion count. Such results are entirely unexpected in view of the teachings of Redmond.

The secondary reference, Thorneycroft et al, evaluated the effect of low dose OC's on SHBG levels and free testosterone. The dose of EE in these OC's was 20 mcg. While Thorneycroft et al reported improvement in acne, it is important to consider the criteria these subjects had to meet to be eligible for inclusion in the study. At page 260, 2nd column, 1st paragraph, Thorneycroft acknowledges that acne was not a criterion for entering the trial. Over 50% of his subjects had less than 15 lesions. Further, in those subjects with more than 15 lesions, the mean was only 31. Thus, nothing in Thorneycroft et al would have allowed one of ordinary skill in the art to predict the results Applicants achieved.

Applicants have lowered the dose of the single component in OC's responsible for the anti-acne effect and have achieved results comparable to Redmond (i.e. groups with moderate and severe acne). Nothing in the prior art would have provided the motivation to lower the dose of estrogen in a treatment for acne. Boissonneault teaches the dosage regimen of claim 9 to provide contraception, not to treat acne. The prior art must provide the motivation to arrive at the claimed invention. Such motivation is lacking.

Withdrawal of the rejections of record and reconsideration is respectfully requested.

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VERSION TO SHOW MARKINGS

(Amended Once) 9. A method of [preventing and treating] reducing the occurrence of acne in a patient in need of such treatment comprising administering an effective amount of 1 mg NA and a gradually increasing dose of EE; 20mcg x 5 days, 30 mcg x 7 days and 35 mcg x 9 days.